UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

Merit Leasing Co., LLC, d/b/a Grande Pointe Healthcare,	)	**CASE NO. 1:23 CV 859**
Plaintiff,	)	**JUDGE PATRICIA A. GAUGHAN**
vs.	)	
Xavier Becerra, Secretary of the U.S. Department of Health and Human Services, *et al.*,	)	**Memorandum of Opinion and Order**
Defendants.		

Introduction

This matter is before the Court upon defendants' Motion to Dismiss for Lack of Jurisdiction. (Doc. 28). This case arises from an overpayment determination assessed by the Medicare program against Grande Pointe. The issue before this Court is whether subject matter jurisdiction exists. For the following reason, the motion is DENIED.

Facts

Plaintiff, Merit Leasing Co., LLC, d/b/a Grande Pointe Healthcare (hereafter, plaintiff or Grande Pointe), filed this Complaint for Declaratory Judgment against defendants Xavier

Becerra, Secretary of the U.S. Department of Health and Human Services; U.S. Department of Health and Human Services; Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services; and the Centers for Medicare & Medicaid Services (collectively, defendants). Plaintiff states that the Complaint seeks relief based on defendants' decision, made prior to initiating an audit of Grande Point, to use a concept called statistical extrapolation which allowed defendants to take the results of an audit of a small sample size of Grande Pointe's claims for payment and extrapolate the results over a larger group of patients and claims which resulted in a much larger amount of repayment owed by Grand Pointe.

According to the allegations of the Complaint and the facts submitted by defendants supported by evidence which may be considered on a Rule 12(b)(1) motion, the facts are as follows. Grande Pointe is a skilled nursing facility certified to provide services for private-pay patients, patients with private insurance, and patients insured by the Medicare and Medicaid programs. Grande Pointe received reimbursement from the Centers for Medicare and Medicaid Services (CMS) for the latter services.

In 2011, Zone Program Integrity Contractor (ZPIC) Advance Med, a private contractor for CMS operating pursuant to the Medicare Act, § 102(a), 42 U.S.C. § 1395kk(a), and the Health Insurance Portability and Accountability Act, § 202(a), 42 U.S.C. § 1395ddd(f)(3), performed an audit of Grande Pointe's Medicare claims. As part of this audit, the contractor reviewed a "randomly selected" sample of 64 of Grande Pointe's billing claims for 107 nursing and therapy services from 2006 to 2008 to determine if they were for medically reasonable and necessary services and if Grande Pointe had used the correct codes.

On December 21, 2011, the contractor notified Grande Pointe that of the 107 services audited 13 services were allowed as billed, 15 services were denied, and 79 services were incorrectly coded. This resulted in CMS's contractor concluding that CMS overpaid Grande Pointe $127,413.78. This represented a billing and payment error rate in this sample size of approximately 93 percent and 32 percent, respectively. Advance Med then employed "statistical extrapolation" to a total of 1,248 claims for the same time period and demanded that Grande Pointe repay CMS in the amount of $2,119,151 which Grande Pointe paid but reserved its right to challenge.

On April 5, 2012, Grande Pointe formally appealed (through redetermination- the first step of the administrative process) the determination in 83 of the 107 services that were reviewed as part of the audit. Grande Pointe received an unfavorable decision.

Grande Pointe then sought reconsideration by the QIC, Maximus Federal Health Services (Maximus)- the second level of administrative review. Plaintiff challenged the "overall sampling and extrapolation work of Advance Med." Plaintiff sought to overturn the overpayment determination and reversal of the determinations on 50 claims. It argued that the overpayment determination was "done incorrectly" and that the "entire extrapolation must be invalidated." And, it argued that Advance Med's sampling methodologies contained errors as Advance Med had not used "best statistical practices" during the sampling and extrapolation calculations, resulting in a sampling that was "invalid."

Maximus issued an unfavorable decision which was later amended for further clarification. The amended decision addressed plaintiff's argument that "there was not a high level of payment error associated with this case and that, therefore, an extrapolation of

payment errors is not appropriate." Maximus concluded that it could not consider the argument because the determination of whether there were high levels of payment error was "not an appealable issue" that could be considered under the Medicare statutes and regulations. Next, Maximus considered plaintiff's arguments "that numerous errors exist in the extrapolation that make the sample fundamentally flawed." It concluded in February 2015 that the extrapolation conducted by Advance Med was valid as it was consistent with the Medicare Program Integrity Manual (PIM) and generally accepted statistical practice. Maximus found that the 50 contested claims were not covered by Medicare. As a result, the amount owed was $2,119,151.

On April 1, 2015, Grande Pointe appealed the decision to an Administrative Law Judge (the third level of administrative review). On May 6, 2015, CMS, through a contractor, issued a revised decision stating that the "original decision was amended to provide further clarification under the explanation of the decisions."

Plaintiff argued to the ALJ that the "extrapolation should be invalid." Plaintiff also argued that Advance Med's underlying "calculation errors" were "sloppy," and that Advance Med had failed to use statistical best practices when performing the statistical sampling and extrapolation. Plaintiff urged the ALJ to "disregard" the "entire sampling and overpayment calculation." Alternatively, plaintiff recommended that if the ALJ "upheld" the sampling and extrapolation, then the ALJ should require the Medicare Administrative Contractors (MACs) to use specific mathematical figures and methodologies to recalculate the overpayment.

Plaintiff continued to challenge the general use of statistical sampling and extrapolation, as well as Advance Med's methods used to determine the overpayment. It also

challenged the 50 claim determinations. In its pre-hearing submission, plaintiff argued that the statistical extrapolation that was used to calculate the overpayment determination was incorrect since there was no high level of payment error, and that CMS should be barred from conducting a new extrapolation following ALJ review.

Two hearings were held before the ALJ. During the first hearing on March 15, 2021, plaintiff and the ALJ discussed plaintiff's challenge to the statistical sampling and extrapolation. Plaintiff argued that Advance Med had inappropriately used statistical sampling and extrapolation because there were issues regarding the payment error rate. The ALJ and plaintiff then discussed what would occur with respect to extrapolation if the ALJ rendered a decision that was only partially favorable to plaintiff. Both the ALJ and plaintiff agreed that, unless plaintiff could prove to the ALJ that there was a "significant degree of error" in the sampling method so that there should be no extrapolation at all, then the statistical extrapolation would be "redone" and would apply to any overpayment determination.

During the second hearing on November 19, 2021, the ALJ and plaintiff focused on the 50 claims. Plaintiff submitted a post-hearing brief, arguing that if each error was corrected for its 50 challenged claim determinations, then there would no longer be a sufficient basis to "warrant[ ] extrapolation under 42 U.S.C. § 1395ddd(f)(3)."

On March 15, 2022, Administrative Law Judge Christian Knapp issued a decision in Grande Pointe's favor on 47 of the 50 appealed claims, and a partially unfavorable decision as to one claim. After the ALJ rendered the decision, the total billing error rate from the sample of 64 claims decreased from approximately 93 percent to 21 percent, and the payment error

rate decreased from approximately 32 percent to 9 percent. This changed the overpayment amount from $127,413.78 to $37,304.69.

As to Advance Med's statistical sampling and extrapolation methodology, the ALJ stated that "sampling creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment." And although plaintiff had argued that other statisticians would not have used the particular sampling methodologies that Advance Med had used, the ALJ concluded that the methods that Advance Med used "did not invalidate the sampling or the extrapolation as drawn and conducted in this case" based on the record evidence. The ALJ noted that Advance Med had properly "defined the universe, the frame, [and] the sampling units; used proper randomization; accurately measured the variables of interest; and used correct formulas for estimation." The ALJ concluded that Advance Med had complied "with all pertinent" Medicare program provisions regarding sampling and extrapolation, and that the statistical sample was "valid with respect to the methodology and overpayment correction."

The notice from the Office of Medicare Hearings & Appeals that accompanied the ALJ's decision informed plaintiff that if it disagreed with the decision, it could file an appeal with the Medicare Appeals Council (Council). Plaintiff was warned that if the decision was not appealed, it would be "binding on all parties," meaning that plaintiff "w[ould] not have the right to ask a federal court to review the decision." The notice advised that to file an appeal with the Council, plaintiff needed to file a written hearing request to the Council within 60 calendar days (plus five days for receipt). It also warned plaintiff that the Council would dismiss a late request for review absent good cause. Thus, plaintiff had until May 19,

2022, to file an appeal, but plaintiff did not do so.

Grand Pointe was ready to pay the $37,304.69 owed, noting that since the billing and payment error rates decreased to approximately 21percent and 9 percent respectively (i.e., less than 50%), the PIM dictated that extrapolation should not be used to expand the alleged overpayment from the sample audited to the entire patient population.

But, Uniform Program Integrity Contractor (UPIC) CoventBridge redid the statistical extrapolation and concluded that plaintiff now owed $417,275.00 in overpayment plus interest in the amount of $46,788.60. Plaintiff was issued a refund as to the original overpayment amount. This represented an extrapolation of the error rate found on the 64-claim sample from 2006 through 2008 to the entire universe of 1,248 claims for that same time period.

Plaintiff e-mailed CGS Administrators, Inc. (CGS) on August 19, 2022, contending that the refund should have been larger and inquiring as to how the overpayment determination was calculated. The same day, plaintiff also faxed a letter to CGS stating that it needed an "explanation of how the [overpayment] amounts were determined/calculated" following the ALJ's decision.

By email of August 23, 2022, CGS responded to plaintiff that, as a result of the appeal decision, the "new recalculated principal overpayment" was $417,275.00 plus interest. By letter of September 27, 2022, CGS informed plaintiff that it had refunded $1,696,700.95 in principal and $1,098,979.39 in interest for a total refund of $2,192,775.56.

CMS continued to withhold the $417,275 plus interest. Upon realizing that CMS intended to use extrapolation (despite internal rules stating that certain requirements needed to

be met to use extrapolation, including an error rate determination of 50% or higher), Grande Pointe wrote to the ALJ on August 23, 2022, attempting to challenge CMS's use of extrapolation after the ALJ's ruling substantially reduced the alleged error rate. Plaintiff requested that the ALJ require the contractor to provide information about the recalculation of the overpayment determination so that it could evaluate "whether or not to bring further appeal." Plaintiff further stated

> Moreover, since we have not received any materials by which we can verify the accuracy of the remittance to Grande Pointe from the MAC [Medicare Administrative Contractor] related to this matter to date and assuming the clock is running on our appeal right, this correspondence will serve as Grande Pointe's notice of appeal as to the recalculation pending its ability to verify and validate the MAC's work product related to the recalculation.

On August 31, 2022, the ALJ responded via voicemail message indicating that the ALJ cannot do anything regarding the effectuation of ALJ orders.

On November 8, 2022, Grande Pointe wrote to CGS contesting the use of extrapolation after the ALJ reduced the error rate to approximately 9 percent and requesting to appeal. The contractor's response on November 18, 2022, tacitly acknowledged that this case did not meet the criteria listed in the Medicare regulations for use of extrapolation. Plaintiff was informed that CMS was entitled to use extrapolation under its PIM because CMS made the decision to do so "prior to creating a statistical sample and issuing a request for medical records from the provider/supplier." Thus, use of extrapolation was approved prior to the start of the investigation and continued on that track regardless of whether the billing/payment error rate decreased. "PIM 8.4.1.4 does not prohibit extrapolation in situations where there ends up being a low payment or billing error rate." CMS refused to allow Grande Pointe to administratively appeal CMS's "*ex ante* decision" to use

extrapolation.

The Complaint alleges that before using extrapolation to determine overpayment amounts there must be a determination of sustained or high level of payment error. 42 U.S.C. § 1395ddd(f)(3); PIM Section 8.4.1.2. A high level of payment error "shall be determined to exist through a variety of means, including, but not limited to: a.) high error rate determinations by the contractor or by other medical reviews (i.e., greater than or equal to 50 percent from a previous pre- or post-payment review)..." Defendants' determinations of "sustained or high levels of payment errors" are "not subject to administrative or judicial review." 42 U.S.C. § 1395ddd(f)(3).

Plaintiff filed its Complaint and seeks a declaratory judgment stating that the extrapolation procedure utilized by CMS without giving providers meaningful process to challenge its use violates the Due Process clause, and an injunction prohibiting CMS from using statistical extrapolation without first providing a meaningful process for providers to challenge the applicability of statistical extrapolation to the case. The Complaint sets forth three claims. Count One alleges a due process violation based on defendants' failure to give Grande Pointe a procedure to challenge the decision to use extrapolation after the ALJ determined that Grande Pointe had less than a 10 percent payment error rate. Count Two alleges a due process challenge to defendants' *ex ante* decision to use extrapolation. Count Three alleges a due process challenge to 42 U.S.C. § 1395ddd(f)(3) (§ 202(a) of the Health Insurance Portability and Accountability Act of 1996) because it prevents administrative or judicial review of defendants' decision. The Complaint invokes federal question jurisdiction under 28 U.S.C. § 1331 on the basis that all of the claims arise under the Constitution.

This matter is now before the Court upon defendants' Motion to Dismiss for Lack of Jurisdiction.

Standard of Review

When a court's subject matter jurisdiction is challenged under Rule 12(b)(1) of the Federal Rules of Civil Procedure, the party seeking to invoke jurisdiction bears the burden of proof. *McNutt v. General Motors Acceptance Corp.*, 298 U.S. 178, 189 (1936); *Rogers v. Stratton*, 798 F.2d 913, 915 (6th Cir. 1986). This burden is not onerous. *Musson Theatrical, Inc. v. Federal Express Corp.*, 89 F.3d 1244, 1248 (6th Cir. 1996). The party need only show that the complaint alleges a substantial claim under federal law. *Id.*

A 12(b)(1) motion to dismiss may constitute either a facial attack or a factual attack. *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). Facial attacks question the sufficiency of the jurisdictional allegations in the complaint. *Id.* Thus, those allegations must be taken as true and construed in the light most favorable to the nonmoving party. *Id.* Factual attacks, however, challenge the actual fact of the court's jurisdiction. *Id.* In such cases, the truthfulness of the complaint is not presumed. *McGee v. East Ohio Gas Co.*, 111 F.2d 979, 982 (S.D. Ohio 2000) (citing *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320 (6th Cir. 1990)). Instead, the Court may weigh any evidence properly before it. *Morrison v. Circuit City Stores, Inc.*, 70 F.Supp.2d 815, 819 (S.D. Ohio 1999) (citing *Ohio Nat'l*, 922 F.2d 320; *Rogers*, 798 F.2d 913).

When presented with a facial attack, the non-moving party "can survive the motion by showing any arguable basis in law for the claim made." *Musson Theatrical*, 89 F.3d at 1248. Thus, such a motion will be granted only if, taking as true all facts alleged in the complaint,

the Court is without subject matter jurisdiction to hear the claim. *Matteson v. Ohio State University*, 2000 WL 1456988 *3 (S.D. Ohio Sept. 27, 2000).

Discussion

Defendants argue that the Court lacks subject matter jurisdiction pursuant to Federal Rule Civil Procedure 12(b)(1) because plaintiff did not complete the final stage of the administrative appeal process review of its claims by the Medicare Appeals Council (hereafter, Council). Because plaintiff did not exhaust the four-level administrative appeal process (redetermination, reconsideration, ALJ review, and review by the Council), plaintiff may not invoke federal court jurisdiction. 42 U.S.C. § 405(g)-(h), 1395ff(b), 42 C.F.R. §§ 405.904(a)(2), 405.1130. The applicable statute provides that if CMS determines that there is a "sustained or high level of payment error" in the claims that the provider submitted for payment from the Medicare program, it may use statistical sampling and extrapolation methods to determine the amount of overpayment to be recouped from the provider. 42 U.S.C. § 1395ddd(f)(3)(A). While the decision to use statistical extrapolation cannot be challenged either through administrative or judicial review, 42 U.S.C. § 1395ddd(f)(3), the overpayment determination itself may still be appealed through the four-level administrative appeal process.

Defendants also maintain that plaintiff knew that the ALJ's partially favorable decision would result in a recalculated overpayment based on extrapolation because this was discussed during the first hearing with the ALJ. Moreover, defendants assert that plaintiff's objection to the use of extrapolation as well as the due process claim arise under the Medicare statute and are subject to the exhaustion requirements. *Shalala v. Ill. Council on Long Term*

Care, 529 U.S. 1, 12-13 (2000) ("§ 405(h) ... demands the 'channeling' of virtually all legal attacks through the agency" including constitutional claims).

Finally, defendants argue that plaintiff is not entitled to a waiver of the exhaustion requirement because plaintiff cannot satisfy any of the applicable factors.

Plaintiff argues that the motion fails for two reasons: failure to exhaust does not deprive a court of subject matter jurisdiction and even if exhaustion applied, this case falls within one of the exceptions. For the following reasons, the Court agrees with plaintiff that dismissal is not appropriate.

Plaintiff maintains that failure to exhaust administrative remedies does not deprive the court of subject matter jurisdiction, and administrative exhaustion under 42 U.S.C. § 405 is a "waivable," "nonjurisdictional element" of the statute. *Smith v. Berryhill,* 139 S.Ct. 1765 (2019); *Carr v. Saul,* 141 S.Ct.1352 (2021) (the exhaustion statute does not impose strict issue exhaustion requirements); *AI Diabetes & Medical Supply v. Azar,* 937 F.3d 613 (6th Cir. 2019)(recognizing precedent that "§ 405(g)'s exhaustion requirement is not a jurisdictional prerequisite for review in federal court."). This Court agrees. The Supreme Court has stated that "exhaustion itself is not a jurisdictional prerequisite." *Smith v. Berryhill*, 139 S. Ct. 1765, 1779 (2019). The court explained:

> Section 405(g), as noted above, provides for judicial review of "any final decision ... made after a hearing." This provision, the Court has explained, contains two separate elements: first, a "jurisdictional" requirement that claims be presented to the agency, and second, a "waivable ... requirement that the administrative remedies prescribed by the Secretary be exhausted." *Mathews v. Eldridge*, 424 U.S. 319, 328, 96 S.Ct. 893, 47 L.Ed.2d 18 (1976). This case involves the latter, nonjurisdictional element of administrative exhaustion. While § 405(g) delegates to the SSA the authority to dictate which steps are generally required, exhaustion of those steps may not only be waived by the agency, but also excused by the courts, see *Bowen v. City of New York*, 476 U.S. 467, 484, 106 S.Ct. 2022, 90 L.Ed.2d 462 (1986); *Eldridg*e, 424 U.S. at 330.

Id. at 1773 1774 (some internal citations omitted). See also *Accident, Inj. & Rehab., PC v. Azar*, 943 F.3d 195, 200 (4th Cir. 2019) ("While the exhaustion requirement of § 405(g) is mandatory, it is well established that it is not jurisdictional. In *Mathews v. Eldridge*, 424 U.S. 319 (1976), the Supreme Court specifically held that the § 405(g) exhaustion requirement is not jurisdictional because its mandate can be waived, whereas a defect in the subject-matter jurisdiction of a court cannot be waived, either by the parties or the court.") [1]

For these reasons, the Court finds that dismissal under 12(b)(1) is not warranted because administrative exhaustion does not strip the Court of jurisdiction. Therefore, the Court need not address whether exhaustion has been waived.

Even if the issue of waiver of exhaustion is reached, the Court agrees with plaintiff that it at least satisfies the futility exception. The Sixth Circuit has recognized:

> In *Bowen v. City of New York*, 476 U.S. 467, 482 86 (1986), the Supreme Court identified three factors to be considered in deciding whether to waive the exhaustion requirement: (1) are the claims at issue collateral to the underlying decision as to eligibility for entitlements; (2) would claimants be irreparably harmed were the exhaustion requirement enforced against them; and (3) would exhaustion of administrative remedies be futile.

Manakee Prof. Med. Transfer Serv., Inc. v. Shalala, 71 F.3d 574, 580 (6th Cir.1995).

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[1] This principle involving failure to exhaust as non-juriusdictional has been applied in Title VII cases. In the same year that the Supreme Court decided *Berryhill*, the court recognized that Title VII's administrative exhaustion requirement is not jurisdictional but is a mandatory claims processing rule. *Fort Bend Cty. v. Davis*, 139 S.Ct 1843 (2019). Thus, the court explained that a court does not lack subject matter jurisdiction when the charge-filing requirement has not been satisfied. Rather, the claims processing rule is mandatory in the sense that the court must enforce it if it is properly raised. But, it can be forfeited if not so raised. The court would still have § 1331 subject matter jurisdiction over the claim. Jurisdiction, however, is never subject to waiver.

Defendants do not appear to dispute plaintiff's assertion that it need not satisfy all three factors to excuse exhaustion.

Courts have explained futility- "[i]f administrative review would come to naught, if any efforts before the agency would be pointless, the courts do not insist that litigants go through the motions of exhausting the claim anyway." *Herr v. U.S. Forest Serv.*, 803 F.3d 809, 822 (6th Cir. 2015) (internal citations and quotations omitted).

Defendants maintain that exhaustion would not have been futile because plaintiff had the opportunity to obtain review and a final decision on its due process claim, its overpayment determination, and the methodology used to calculate that determination, but it did not do so.

The Court agrees with plaintiff that futility has been demonstrated.[2] As discussed above, plaintiff maintains that while defendants assert that it abandoned its argument regarding statistical sampling and extrapolation when it did not appeal, the issue before the ALJ about extrapolation concerned statistical modeling and not the use of extrapolation after a low error rate is determined. It is clear that use of extrapolation after the error rate is reduced to less than 10 percent was unreviewable during the administrative process. Plaintiff points out that CMS has always maintained that parties cannot challenge the use of extrapolation in the administrative process. And, while defendants maintain that plaintiff could have appealed to the Council if it was dissatisfied with the ALJ's decision, plaintiff was not dissatisfied until CMS persisted in seeking a recovery based upon extrapolation despite a low error rate. Moreover, plaintiff states that it is still not dissatisfied with the ALJ's decision,

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[2] Because futility is satisfied, the Court need not reach whether the "collateral" exception to waiver applies or whether this case falls within the "no review" exception.

but seeks here to challenge the continued use of an *ex ante* determination (approved at the onset of a case and unreviewable after that) by a private contractor to apply extrapolation after a low error rate had been determined, undermining the validity of that forecasted error rate.

Since plaintiff could not have made its challenge to the determination of sustained or high levels of payment errors in the administrative process, an appeal would have been futile.

For these reasons, dismissal for lack of subject matter jurisdiction is not warranted.

Conclusion

For the foregoing reasons, defendants' Motion to Dismiss for Lack of Jurisdiction is denied.

IT IS SO ORDERED.

/s/ Patricia A. Gaughan
PATRICIA A. GAUGHAN
United States District Judge

Dated: 12/1/23